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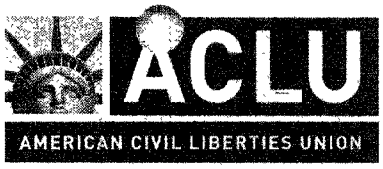

November 1, 2005

Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Advance Notice for Proposed Rulemaking, Docket Number 2005N-0345 Regarding Barr Laboratories' "Plan B" Petition

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TREASURER

Dear Acting Commissioner von Eschenbach:

In response to the Advance Notice for Proposed Rulemaking, docket number 2005N-0345, the ACLU urges the Food and Drug Administration ("FDA") to suspend the proposed rulemaking process immediately and to approve without further delay Barr Laboratories' application to market Plan B, a form of emergency contraception, without a prescription.

A rulemaking proceeding is neither necessary nor legally required to approve Barr's petition for over-the-counter status for Plan B. Increased access to Plan B would help prevent unintended pregnancies, reduce abortions, and promote women's reproductive health and rights. The FDA's continued delay in reaching a decision on this application permits politics to trump science and amounts to a failure to meet the agency's obligation to promote and protect women's health. Moreover, the agency's proposal for a two-tiered system of availability for Plan B would undermine the privacy rights of women of all ages who seek access to this critical drug. The ACLU urges the FDA to abandon this two-tiered approach and to permit women of all ages to purchase Plan B without a prescription.

Background

Plan B was approved by the FDA in 1999 for use as a contraceptive. According to the approved labeling, Plan B decreases the risk of unintended pregnancy resulting from contraceptive failure or unprotected intercourse by

89%.[1] In April 2003, Barr Laboratories, Plan B's manufacturer, filed an application with the FDA to make Plan B available over the counter.

In December 2003, two FDA advisory committees composed of medical experts voted overwhelmingly (23-4) in favor of granting Barr's petition. In reaching this conclusion, the advisory committees considered extensive scientific and social science evidence indicating that the drug is safe and effective and that over-the-counter access to it would serve the public health. Indeed, the FDA panel unanimously agreed both that Plan B was safe for use in a non-prescription setting and that there was no evidence that over-the-counter availability leads sexually active individuals to substitute emergency contraception for regular use of other contraceptive methods. *See* Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs 354-64 (Dec. 16, 2003).[2] FDA staff in the Center for Drug Evaluation and Research also recommended that Plan B be approved for over-the-counter use. *See* Gardiner Harris, Morning-After-Pill Ruling Defies Norm, *New York Times*, May 8, 2004, at A13.

Despite these views, in May 2004, the FDA rejected Barr's application, asserting that there was insufficient evidence that Plan B could be used safely without a prescription by women under sixteen. Based on the concerns expressed in the agency's non-approvable letter, Barr submitted a supplemental application proposing a two-tiered structure under which Plan B would be made available over-the-counter to women sixteen years of age or older, but only with a prescription to those under sixteen. The agency failed to act on this revised application for more than a year. On August 26, 2005, the FDA concluded, without warning, that Plan B should only be available over-the-counter to women seventeen and older. The agency also announced that it would not act on Barr's petition and instead would initiate a 60-day public comment and rulemaking process with no timetable for making a decision.

No Rulemaking Proceeding Is Required to Approve Barr's Petition.

A rulemaking proceeding is neither necessary nor legally required for the FDA to approve Barr's petition for over-the-counter status for Plan B. Although the FDA may change a drug's status from prescription to over-the-counter via a rulemaking process, as stated in the Advanced Notice of Proposed Rulemaking here, it may also change a drug's status by means of an agency order, in this case by approving a Supplemental New Drug

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[1] FDA, Center for Drug Research and Evaluation, Medical Review, NDA 21045 (Plan B), available at http://www.fda.gov/cder/foi/nda/99/21-045_Plan%20B_medr.pdf.

[2] Available at www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.pdf.

Application by authority granted under the Food, Drug, and Cosmetic Act.[3] There is no compelling reason to require a rulemaking proceeding to evaluate Barr's petition.

The FDA already possesses sufficient information to conclude that Plan B is safe for use without a prescription. Plan B meets the FDA's criteria for determining that a drug is appropriate for over-the-counter use. It treats a condition that patients can diagnose themselves; it is safe and effective when used without direct prescriber supervision; and the drug's label adequately explains potential adverse effects and conditions of use. Plan B is easy to use, is not addictive, and has no known health hazards when self-administered. The drug has virtually no contraindications and few side effects. There is simply no compelling medical rationale for restricting Plan B to prescription-only use. The rulemaking process should therefore be suspended.

The FDA's Refusal to Approve Barr's Petition Cannot Be Justified By Medical Science.

The FDA's continued refusal to act on Barr's petition flies in the face of recommendations by two FDA Advisory Committees, FDA officials, and major medical groups. Two of the FDA's own advisory committees voted overwhelmingly to allow Plan B to be made available without a prescription. In concluding that emergency contraceptives are safe and effective, the FDA advisory panel considered a study showing that easy access to such contraceptives does not cause adolescents to have more unprotected sex or to stop using contraception.

The advisory committee's recommendation that Plan B be approved for non-prescription use was supported by the staff of the FDA. Indeed, memoranda from the FDA staff show the extent of disagreement with the agency's final decision to delay approval indefinitely: One senior FDA employee described the reasoning used to justify denying immediate approval for Plan B as "speculative and unbalanced." Marc Kaufman, Staff Scientists Reject FDA's Plan B Reasoning, *Washington Post*, June 18, 2004, at A02. Dr. Susan Wood, the former director of FDA's Office of Women's Health who resigned in protest over the agency's refusal to act on the petition, explained, "[S]cientific and clinical evidence, fully evaluated and recommended for approval by the professional staff [at the FDA], has been overruled." *F.D.A. Aide Quits in Protest of Morning-After Pill Decision,* Associated Press, August 31, 2005.

Moreover, major medical groups, including the American College of Obstetricians and Gynecologists, the American Medical Association, and the

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[3] *See SEC v. Chenery*, 332 U.S. 194, 202-203 (1947) (an administrative agency has the authority to use either rulemaking or other authority granted it by Congress to make decisions).

American Public Health Association, also supported making Plan B more readily accessible.

By refusing to act on Barr's application, the FDA ignored the scientific evidence and has turned what should be a science-based decision on a drug approval into a political game.

Over-the-Counter Availability Ensures Access to Emergency Contraception for the Many Women Who Need It.

Nearly half of all pregnancies in the United States are unintended. *See* Alan Guttmacher Institute, Questions About Pregnancy, Contraception and Abortion (2004).[4] For the women who face a potential unintended pregnancy, widespread and timely access to emergency contraception is critical.

Emergency contraception must be taken within 72 to 120 hours after unprotected intercourse, but experts agree that it is more effective the sooner it is taken. *See* Charlotte Ellertson et al., Extending the Time Limit for Starting the Yuzpe Regimen of Emergency Contraception to 120 Hours, 101 Obstet. Gynecol. 1168, 1168 (2003). This narrow window makes ready access to emergency contraception critical. The current requirement that emergency contraception only be dispensed with a doctor's prescription acts as significant barrier to obtaining this safe and effective method of birth control. A woman who has just experienced unprotected sex, contraceptive failure, or sexual assault, must find an available physician who can and will fill a Plan B prescription; obtain the prescription; find a pharmacy and pharmacist that will dispense the drug; fill the prescription; and take the medication -- all "while the time window for efficacy is closing." Alastair Wood, et al., A Sad Day for Science at the FDA, 535 N. Engl. J. Med. 1197 (2005). For women who cannot afford a doctor's appointment, whose doctor's office is closed during the critical period, or who cannot obtain an appointment within the short window, the prescription requirement serves as a major impediment to obtaining the drug within the necessary time frame.

Denied access to emergency contraception, some women will face a choice of either continuing an unwanted pregnancy or having an abortion. *See* Rachel K. Jones et al., Contraceptive Use Among U.S. Women Having Abortions in 2000-2001, 34 Persp. on Sex & Reprod. Health 294, 300 (2002) (estimating 51,000 abortions were prevented in 2000 alone because of emergency contraceptive use). Emergency contraception prevents pregnancy, but does not disrupt an existing pregnancy. Moreover, emergency contraception is safe: to date, millions of women have used emergency contraception with no serious side effects or contraindications that would endanger their health. *See* World Health Organization, Emergency Contraception: A Guide for Service Delivery (1998).

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[4] Available at http://www.agi-usa.org/in-the-know/pregnancy.html.

Age-Based Restrictions Are Unnecessary, Will Infringe Women's Privacy Rights, and Will Impede Women of All Ages from Obtaining Plan B.

There is no scientific evidence that women under the age of seventeen are unable to use Plan B safely without a prescription. Data presented to the FDA in conjunction with Barr's original application demonstrated that Plan B is safe for young women and that more open access to Plan B does not increase risk-taking behavior, such as having unprotected sex, among teens. *See* Melanie Gold, Testimony at the Meeting of the FDA Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs 155-57 (Dec. 16, 2003).[5] Indeed, the FDA has not identified any data indicating that Plan B poses a health threat to younger women. *See* Alastair Wood, et al., A Sad Day for Science at the FDA, 535 N. Engl. J. Med. 1197, 1198 (2005).

And, significantly, imposing age-based restrictions on Plan B will breach the privacy rights of all women who seek access to this critical drug. A two-tiered, age-based structure will require pharmacies that sell Plan B over-the-counter to impose mandatory proof of age requirements on all women who purchase the drug. Such a requirement, which is not placed on other over-the-counter drugs, constitutes an unwarranted invasion of a woman's privacy. The prospect of being forced to produce public identification while purchasing a drug as personal and intimate as emergency contraception is likely to deter women of all ages from purchasing the drug. Given Plan B's demonstrated safety record, such an invasion serves no legitimate purpose, and indeed may only humiliate a woman who has just experienced contraceptive failure, unprotected sex, or sexual assault.

Improved Access to Emergency Contraception Is Particularly Critical for Sexual Assault Survivors.

Over-the-counter access to emergency contraception is especially important for sexual assault survivors. Every year, approximately 25,000 pregnancies occur because of sexual assault. *See* Felicia Stewart et al., Prevention of Pregnancy Resulting from Rape: A Neglected Preventive Health Measure, 19 Am. J. Preventive Med. 228, 228 (2000). Emergency contraception could prevent approximately 22,000 of these pregnancies. *Id.* at 229. Yet in many areas, more than half of hospital emergency rooms fail to provide emergency contraception to sexual assault patients routinely. *See* ACLU Reproductive Freedom Project Briefing Paper, Preventing Pregnancy after Rape: Emergency Care Facilities Put Women at Risk (2004).[6] The

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[5] Available at www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.pdf.

[6] Available at http://www.aclu.org/ReproductiveRights/ReproductiveRights.cfm?ID=17212&c=30.

prescription requirement serves as a major barrier to access to emergency contraception for sexual assault survivors in these areas. If a woman is denied access to emergency contraception in the emergency room to which she is initially brought, she must then somehow track down another doctor, answer more personal and painful questions, and find a pharmacy to fill her prescription, all within 72 to 120 hours of the assault. Ready availability of emergency contraception without a doctor's prescription would mean that at least one injury from the assault, the possibility of pregnancy, could be quickly and safely alleviated.

Conclusion

Approving over-the-counter access to Plan B will promote public health, prevent unintended pregnancies, and reduce abortions. Age-based restrictions, which are not medically warranted, will chill the ability of women of all ages to access Plan B. Given the strong support for the petition expressed by the FDA's independent committee of experts, FDA staff, and major medical groups, the ACLU urges you to suspend the rulemaking process and to act without further delay to approve over-the-counter status for Plan B emergency contraception.

AMERICAN CIVIL
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Sincerely,

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